



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Office of the Commissioner

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of the Commissioner (OC), and Office of Operations (OO) have modified their structures. This new organizational structure was approved by the Secretary of Health and Human Services on January 10, 2017 and effective on February 11, 2017.

FOR FURTHER INFORMATION CONTACT: Segaran Pillai, Ph.D, Director, Office of Laboratory Science and Safety, Office of the Commissioner, Food and Drug Administration, White Oak Bldg. 1, rm. 2218, 10903 New Hampshire Ave, Silver Spring, MD 20993-0002, 240-402-2856.

SUPPLEMENTARY INFORMATION: Part D, Chapter D-B, (Food and Drug Administration), the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, 60 FR 56606, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007, 74 FR 41713, August 18, 2009, and 76 FR 45270, July 28, 2011) is amended to reflect the reorganization of the Office of the Commissioner and the Office of Operations.

This reorganization establishes the Office of Laboratory Science and Safety, and will authorize the consolidation of the laboratory science, safety functions, and program

activities across FDA under one organizational component that will report directly to the Office of the Commissioner. The Employee Safety and Environmental Management Staff will be realigned from the Office of Safety, Security and Crisis Management to the Office of Laboratory Science and Safety. As a result of the staff realignment the Office of Safety, Security and Crisis Management within the Office of Operations will be re-titled to the Office of Security and Emergency Management. The Office of Crisis Management within the newly titled Office of Security and Emergency Management will change its title to the Office of Emergency Management. Additionally, the Office of Security and Emergency Management has established the Emergency Planning, Evaluation, and Exercise Staff, and the Program Operations and Coordination Staff within the Office of Emergency Management.

The Food and Drug Administration, Office of the Commissioner (OC), has been restructured as follows:

DA. ORGANIZATION. The Office of the Commissioner is headed by the Commissioner of Food and Drugs and includes the following organizational units:

Office of the Commissioner (DA)

Office of the Chief Counsel (DAA)

Office of the Executive Secretariat (DAB)

Executive Secretariat Staff (DAB1)

Freedom of Information Staff (DAB2)

Dockets Management Staff (DAB3)

Office of the Chief Scientist (DAE)

National Center for Toxicological Research (DAEC)

Office of the Center Director (DAECA)

Office of Management (DAECB)

Planning and Resource Management Staff (DAECBA)

Office of Research (DAECC)

Division of Biochemical Toxicology (DAECCA)

Division of Genetic and Molecular Toxicology (DAECCB)

Genetic Toxicology Lab (DAECCB1)

Division of Microbiology (DAECCD)

Division of Systems Biology (DAECCE)

Division of Neurotoxicology (DAECCF)

Division of Bioinformatics and Biostatistics (DAECCH)

Office of Scientific Coordination (DAECF)

Office of Counter-Terrorism and Emerging Threats (DAEG)

Office of Scientific Integrity (DAEH)

Office of Regulatory Science and Innovation (DAEI)

Division of Science Innovation and Critical Path (DAEIA)

Division of Scientific Computing and Medical Information (DAEIB)

Office of Scientific Professional Development (DAEJ)

Office of Health Informatics (DAEK)

Office of the Counselor to the Commissioner (DAR)

Office of Women's Health (DAS)

Office of External Affairs (DAU)

Web and Digital Media Staff (DAU1)

Administrative Management Staff (DAU2)

Office of Media Affairs (DAUA)

Web Communications Staff (DAUA2)

Office of Communications (DAUB)

Communications Staff (DAUB1)

FDA History Office (DAUB2)

Office of Health and Constituent Affairs (DAUC)

Office of Minority Health (DAY)

Office of Laboratory Science and Safety (DAZ)

Employee Safety and Environmental Management Staff (DAZ1)

The Food and Drug Administration, Office of Operations (OO), has been restructured as follows:

DMM. ORGANIZATION. The Office of Operations is headed by the Deputy Commissioner for Operations and Chief Operating Officer and includes the following organizational units:

Office of Operations (DMM)

Office of Business Services (DMM1)

Business Operations Staff (DMM11)

Employee Resource and Information Center (DMM1A)

Division of Ethics and Integrity (DMM3)

Ombudsman and Conflict Prevention and Resolutions Staff (DMM4)

Office of Equal Employment Opportunity (DMMA)

Compliance Staff (DMMA1)

Diversity Staff (DMMA3)

Office of Finance, Budget and Acquisitions (DMMD)

Office of Budget (DMMDA)

Division of Budget Formulation (DMMDAA)

Division of Budget Execution and Control (DMMDAB)

Office of Acquisition and Grant Services (DMMDB)

Division of Acquisition Operations (DMMDBA)

Service Contract Branch (DMMDBA1)

Contract Operations Branch (DMMDBA2)

Division of Acquisition Programs (DMMDBB)

Scientific Support Branch (DMMDBB1)

Field Operations Branch (DMMDBB2)

Facilities Support Branch (DMMDBB3)

Division of Regulatory Inspections Acquisitions and Grants and Assistance Management (DMMDBC)

Grants Management Branch (DMMDBC1)

Regulatory Inspections and Acquisitions Branch (DMMDBC2)

Division of Information Technology Acquisitions (DMMDBD)

Information Technology Acquisitions Branch (DMMDBD1)

Systems Technology Acquisitions Branch (DMMDBD2)

Division of Policy, Systems, and Program Support (DMMDBE)

Office of Financial Operations and Policy (DMMDC)

Office of Financial Management (DMMDCA)

Internal Controls, Compliance and Oversight Staff (DMMDCA1)

Business Transformation, Administration and Management Staff (DMMDCA2)

User Fee Staff (DMMDCA3)

Financial Systems Support Staff (DMMDCA4)

Division of Accounting (DMMDCAB)

Division of Travel Services (DMMDCAC)

Division of Payment Services (DMMDCAD)

Office of Human Resources (DMME)

Commissioned Corps Affairs Staff (DMME6)

Management Analysis Services Staff (DMME7)

Business Operations Staff (DMME8)

Division of Workforce Relations (DMMEB)

Employee and Labor Relations Branch I (DMMEB1)

Employee and Labor Relations Branch II (DMMEB2)

Division of Policy, Programs, and Executive Resources (DMMEC)

Policy Branch (DMMEC1)

Executive Resources Branch (DMMEC2)

Accountability Branch (DMMEC3)

Division of Enterprise Support Services (DMMED)

Resources and Information Branch (DMMED1)

Systems and Records Management Branch (DMMED2)

Benefits Branch (DMMED3)

FDA University (DMMEF)

Division of Human Resource Services for Office of the Commissioner/Office of Operations (DMMEG)

Office of the Commissioner/NCTR Customer Solutions Branch (DMMEG1)

Office of Operations Customer Solutions Branch (DMMEG2)

Division of Human Resource Services for Office of Medical Products and Tobacco (DMMEH)

CDRH Customer Solutions Branch (DMMEH1)

CBER and NCTR Customer Solutions Branch (DMMEH2)

CDER Customer Solutions Branch (DMMEH3)

CTP Customer Solutions Branch (DMMEH4)

Division of Human Resource Services for the OFVM/OGROP (DMMEI)

CFSAN/CVM Customer Solutions Branch (DMMEI1)

ORA/OIP Customer Solutions Branch (DMMEI2)

Office of Facilities, Engineering, and Mission Support Services (DMMF)

Jefferson Laboratories Complex Staff (DMMF1)

Facilities Program Staff (DMMF2)

Division of Operations Management and Community Relations (DMMFA)

Logistics and Transportation Management Branch (DMMFA1)

Facilities Maintenance and Operations Branch (DMMFA2)

Auxiliary Program Management Branch (DMMFA3)

Division of Planning, Engineering and Space Management (DMMFB)

Portfolio and Space Management Branch (DMMFB1)

Engineering Management Branch (DMMFB2)

Office of Information Management and Technology (DMMH)

Office of Information Management (DMMHA)

Information Security Staff (DMMHA1)

Knowledge Management Staff (DMMHA2)

Enterprise Architecture and Technology Innovation Staff (DMMHA3)

Office of Technology and Delivery (DMMHAA)

Delivery Management and Support Staff (DMMHAA1)

Divisions of Infrastructure Operations (DMMHAAA)

Infrastructure Management Services Staff (DMMHAAA1)

Implementation Branch (DMMHAAA2)

Infrastructure Engineering Branch (DMMHAAA3)

Systems Monitoring and Response Branch (DMMHAAA4)

Systems Operations Branch (DMMHAAA5)

Network and Communications Operations Branch (DMMHAAA6)

Division of Application Services (DMMHAAB)

Application Management Services Staff (DMMHAAB1)

Data Management and Operations Branch (DMMHAAB2)

Medical Products Branch (DMMHAAB3)

OC/CVM/CTP Branch (DMMHAAB4)

ORA/CFSAN Branch (DMMHAAB5)

Enterprise Application Branch (DMMHAAB6)

Division of Delivery Management and Support (DMMHAAC)

Delivery Management Branch (DMMHAAC1)

Process Management and Control Branch (DMMHAAC2)

Office of Business and Customer Assurance (DMMHAB)

Records, eDiscovery and Risk Management Staff (DMMHAB1)

Division of Business Partnership and Support (DMMHABA)

Internet and Intranet Branch (DMMHABA1)

Call Center Branch (DMMHABA2)

Regional Support Branch (DMMHABA3)

Property, Receiving and Distribution Branch (DMMHABA4)

Division of Management Services (DMMHABB)

Internal Services and Response Branch (DMMHABB2)

Acquisitions Services Branch (DMMHABB3)

Human Capital and Visual Media Branch (DMMHABB4)

Office of Enterprise Portfolio Management (DMMHAC)

Office of Security and Emergency Management (DMMJ)

Office of Security Operations (DMMJA)

Office of Emergency Management (DMMJB)

Emergency Planning, Evaluation, and Exercise Staff (DMMJB1)

Program Operations and Coordination Staff (DMMJB2)

Office of Emergency Operations (DMMJBA)

I. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

II. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide (SMG). Persons interested in seeing the complete Staff Manual Guide can find it on FDA's website at: <https://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm>.

(Authority: 44 U.S.C. 3101)

Dated: July 17, 2017.

Thomas E. Price,

Secretary of Health and Human Services

[FR Doc. 2017-15564 Filed: 7/24/2017 8:45 am; Publication Date: 7/25/2017]